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Please type a plus sign (+) inside this box → ☐**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Application Number	10/695,194
Filing Date	October 28, 2003
First Named Inventor	Hochstrasser
Group Art Unit	1645
Examiner Name	Swartz, Rodney P
Attorney Docket Number	A36054-PCT-USA-A (072874)

Total Number of Pages in This Submission

ENCLOSURES (check all that apply)

- | | | |
|--|---|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form
<input type="checkbox"/> Fee Attached
<input checked="" type="checkbox"/> Amendment / Reply
<input type="checkbox"/> After Final
<input type="checkbox"/> Affidavits/declaration(s)
<input type="checkbox"/> Extension of Time Request
<input type="checkbox"/> Express Abandonment Request
<input type="checkbox"/> Information Disclosure Statement
<input type="checkbox"/> Certified Copy of Priority Document(s)
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application)
<input type="checkbox"/> Drawing(s)
<input type="checkbox"/> Licensing-related Papers
<input type="checkbox"/> Petition
<input type="checkbox"/> Petition to Convert to a Provisional Application
<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address
<input type="checkbox"/> Terminal Disclaimer
<input type="checkbox"/> Request for Refund
<input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
Return receipt postcard; |
|--|---|---|

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENTFirm
or
Individual nameBakerBotts LLP
30 Rockefeller Plaza
New York, NY 10112

Signature

Rochelle K. Seide

Att Name: Rochelle K. Seide
PTO Reg: 32,300

Date

January 20, 2005

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date: January 20, 2005

Typed or printed name

Rochelle K. Seide

Signature

Rochelle K. Seide

Date January 20, 2005

BAKER BOTTS LLP

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$0)

Complete if Known

Application Number	10/695,194
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First Named Inventor	Hochstrasser
Examiner Name	Swartz, Rodney P
Art Unit	1645
Attorney Docket No.	A36054-PCT-USA-A (072874)

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None
☐ Deposit Account:
 Deposit
Account
Number
Deposit
Account
Name

02-4377

Baker Botts LLP

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee required under 37CFR 1.16 and 1.17☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$0)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	- 20 = 0	X	0
Multiple Dependent	- 3 = 0	X	0

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$0)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65			Surcharge - late filing fee or oath	
1052 50	2052 25			Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130			Non-English specification	
1812 2,520	1812 2,520			For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*			Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*			Requesting publication of SIR after Examiner action	
1251 110	2251 55			Extension for reply within first month	
1252 420	2252 210			Extension for reply within second month	
1253 950	2253 475			Extension for reply within third month	0
1254 1,480	2254 740			Extension for reply within fourth month	
1255 2,010	2255 1,005			Extension for reply within fifth month	
1401 330	2401 165			Notice of Appeal	
1402 330	2402 165			Filing a brief in support of an appeal	
1403 290	2403 145			Request for oral hearing	
1451 1,510	1451 1,510			Petition to institute a public use proceeding	
1452 110	2452 55			Petition to revive - unavoidable	
1453 1,300	2453 650			Petition to revive - unintentional	
1501 1,330	2501 665			Utility issue fee (or reissue)	
1502 480	2502 240			Design issue fee	
1503 630	2503 315			Plant issue fee	
1460 130	1460 130			Petitions to the Commissioner	
1807 50	1807 50			Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180			Submission of Information Disclosure Stmt	
8021 40	8021 40			Recording each patent assignment per property (times number of properties)	
1809 770	2809 385			Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385			For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385			Request for Continued Examination (RCE)	
1802 900	1802 900			Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$0)

SUBMITTED BY

Name (Print/Type)

Rochelle K. Seide

Registration No.
(Attorney/Agent)

32,300

(Complete if applicable)

Telephone 212 408 2626

Signature

Rochelle K. Seide

Date

January 20, 2005

BAKER BOTTS LLP

Attorney Docket Number: A36054-PCT-USA-A (072874).

Title: DIAGNOSTIC METHOD FOR TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

Use Space Below for Additional Information:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s) : Hochstrasser et al.
Serial No. : 10/695,194
For : DIAGNOSTIC METHOD FOR TRANSMISSIBLE SPONGIFORM
ENCEPHALOPATHIES
Filed : October 28, 2003
Examiner : Swartz, Rodney P
Art Unit : 1645

RESPONSE TO RESTRICTION REQUIREMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450.

January 20, 2005
Date of Deposit

Rochelle K. Seide
Attorney Name

Rochelle K. Seide
Signature

32,300

Registration No.

January 20, 2005
Date of Signature

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is submitted in response to the Office Communication dated December 20, 2004 in the above-identified application. Since the Applicants have filed this response within the shortened statutory period for reply of one month, this paper is timely filed. Applicants therefore believe that no fee is due in the submission of this paper.

The Examiner has issued a restriction requirement under 35 U.S.C. §121 and requires selection of one of six groups of claims for prosecution in this application:

Group I: Claims 1-19, 21, 22 and 29-46, drawn to method and kit for diagnosis of

TSE by detecting polypeptide;

Group II: Claim 20, drawn to method for diagnosis of TSE by detecting antibody;

Group III: Claim 20, drawn to therapy using polypeptide;

Group IV: Claims 21 and 22, drawn to therapy using antibody;

Group V: Claims 23-28, drawn to device using antibody; and

Group VI: Claim 47, drawn to normal bovine animals.

The Examiner asserts that the inventions of Group I and II are drawn to two distinct methods. The Examiner alleges that the invention of Group I is a method for detecting polypeptides while Invention II is a method for detecting antibodies.

The Examiner alleges that the inventions of Group I and III are drawn to two distinct methods, namely for the diagnosis of disease or a method of therapy respectively.

The Examiner alleges that inventions of Group I and IV are drawn to two distinct methods using different reagents. The claims of Group I are allegedly drawn to a method of detecting disease by detecting polypeptides while claims of Group IV are drawn to a method of therapy for infected hosts utilizing antibodies.

The claims of Group I and IV are allegedly distinct since it can be shown that the process as claimed can be performed by another with a materially different apparatus. The Examiner alleges that the process of Invention I can be performed with a materially different apparatus i.e. by mass spectrometry.

It is alleged by the Examiner that the claims of Groups I and VI are drawn to patentably distinct inventions since Invention I is a method for diagnosis of disease while Invention IV is a normal bovine animal.

The Inventions of Groups I and IV, Groups II and III and Groups II and III are allegedly drawn to different methods utilizing different reagents and having different end results.

The Examiner alleges that the inventions of Groups II and V are drawn to different methods and device. Claims of Invention II are drawn to a method of diagnosis by detecting antibody while Invention V is a device with bound antibody for detecting polypeptides.

The Examiner alleges that the claims of Groups II and VI are drawn to patentable distinct inventions wherein Invention II is a method for diagnosis and Invention VI is a normal bovine animal.

The Examiner alleges that the claims of Groups III and IV are drawn to different methods, utilizing different reagents and different method steps.

Invention III and V are allegedly drawn to structurally and functionally distinct inventions wherein claims of Invention III is drawn to polypeptides while claims of invention V is a device with bound antibody.

The Inventions of Groups III and VI are allegedly patentably distinct inventions. Group III is allegedly a method of therapy and Group VI is a normal bovine animal.

The Examiner alleges that the claims of Groups IV and V are drawn to different methods which utilize different reagents and method steps.

The Examiner alleges that the claims of Groups IV and VI are drawn to patentably distinct inventions. Group IV is a method of therapy and Group VI is a normal bovine animal.

The Examiner alleges that the claims of Groups V and VI are drawn to structurally and functionally distinct products. Invention V is a device and Invention VI is a normal bovine animal.

Furthermore, the Examiner alleges that the inventions have separate status in the art due to their different classification. The Examiner further allege that in instances where the classification are the same, the non-patent literature searches are not co-extensive, causing the searches to be burdensome.

Applicants respectfully traverse. There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP § 802.01, § 806.04 and § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and (B) There must be a serious burden on the Examiner if restriction is required (see MPEP § 808.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02). The term "independent" (*i.e.*, not dependent) means that there *is no disclosed relationship* between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect. (Emphasis supplied, MPEP § 802.01). Moreover, MPEP § 803 states that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner *must* examine it on the merits, even though it contains claims to distinct or independent inventions." (Emphasis supplied).

Applicants submit that the inventions of Group I are clearly connected to Groups II and III. All three groups comprise of a method of diagnosis (Claims 1-19, 20, 21, 22, 29-46) prognosis or therapy (Claims 20-22) of transmissible spongiform encephalopathy (TSE) or related conditions by detecting or utilizing a polypeptide differentially contained in the body fluid of TSE-infected subjects. The inventions of Group IV and V are clearly connected to the invention of Groups I, II and III. The steps comprising the method recited in the claims of Group I, II and III form the basis of the inventions of Group IV and V. Applicants submit that the "assay device for use in diagnosis" as recited in claims of Group V, encompasses the invention of Groups I to IV. The claim of Group VI is dependent from claim 43 (Group I). The applicants submit that method

of diagnosis of claim 43 shares a common goal with the invention of Group VI in establishing the disease status of a set of subjects on which such testing is performed.

In conclusion, Applicant asserts that the claims of Groups I-VI are connected by a disclosed relationship and, therefore, should be examined together. Applicants further submit that the claims are connected by a single, searchable unifying relationship, and that the Examiner would not, therefore, be seriously burdened by searching and examining the claims of these groups in a single application. Accordingly, Applicants request withdrawal of the restriction requirement.

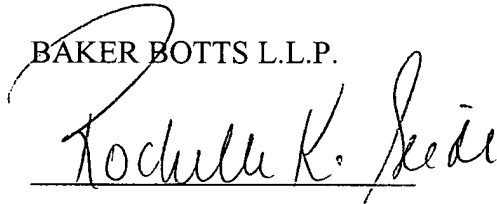
Under 37 C.F.R. §1.143 the applicants are required to reply to the Restriction Requirement by including an election of the invention to be examined. Applicants elect Group I, consisting of Claims 1-19, 21, 22 and 29-46 drawn to method and kit for diagnosis of TSE by detecting polypeptide, classified in class 436, subclass 501. Applicants submit that the election is made without prejudice to the prosecution of the subject matter of non-elected claims in divisional, continuation and continuation-in-part applications.

Applicants do not believe that any additional fee is required in connection with the submission of this document. Should any additional fees be required, the Commissioner is hereby authorized to charge any additional fees to Deposit Account 02-4377. A duplicate copy of this communication is provided.

Respectfully submitted,

BAKER BOTTS L.L.P.

By:

A handwritten signature in dark ink, appearing to read "Rochelle K. Seide", is written over a horizontal line.

Rochelle K. Seide
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